

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	10/098,514
		Filing Date	March 11, 2002
		First Named Inventor	CHANG, Sandra P.
		Group Art Unit	1645
Examiner Name		Attorney Docket Number	A-71339/RFT/ITAL/NBC (464334-142)
Sheet	1	of	4

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.	U.S. Patent Document Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
~	A1	4,745,051	05-1988	Smith et al.	
~	A2	6,270,800 B1	08-07-2001	Speaker et al.	
~	A3	6,420,523 B1	07-16-2002	Chang et al.	
	A4				
	A5				

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document Country Code ² Number ³ Kind Code ⁴ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
~	B1	EP 0 329 257	08-1989	MICROGENESYS, INC.	RECEIVED AUG 14 2003 TECH CENTER 1600/2000	
	B2					
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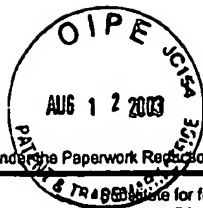
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~	C1 \	ANNON, "Human Clinical Trials of Plant Engineered as Vaccine are Successful; May Usher in New Era for Plant/Pharmaceutical Research," Am. Soc. Plant Phys. Newsletter 25(3):9 (1998)				
~	C2 \	BEVAN M., "Binary Agrobacterium vectors for plant transformation." Nucleic Acids Res. 1984 Nov 26;12(22):8711-21.				
~	C3 \	BURGHAUS PA, et al., "Immunization of Aotus nancymai with recombinant C terminus of Plasmodium falciparum merozoite surface protein 1 in liposomes and alum adjuvant does not induce protection against a challenge infection." Infect Immun. 1996 Sep;64(9):3614-9.				
~	C4 \	CHANG SP, et al., "A carboxyl-terminal fragment of Plasmodium falciparum gp195 expressed by a recombinant baculovirus induces antibodies that completely inhibit parasite growth." J Immunol. 1992 Jul 15;149(2):548-55.				
~	C5 \	CHANG SP, et al., "Generalized immunological recognition of the major merozoite surface antigen (gp195) of Plasmodium falciparum." Proc Natl Acad Sci U S A. 1989 Aug;86(16):6343-7.				
~	C6 \	CHANG SP, et al., "A recombinant baculovirus 42-kilodalton C-terminal fragment of Plasmodium falciparum merozoite surface protein 1 protects Aotus monkeys against malaria." Infect Immun. 1996 Jan;64(1):253-61.				
~	C7	CHEUNG et al. "Immunization with synthetic peptides of a Plasmodium falciparum surface antigen induces antimerozoite antibodies," Proc. Natl. Acad. Sci. USA 83:8328 (1986).				
~	C8 \	DATLA, RSS, et al., "Improved high-level constitutive foreign gene expression in plants using an AMV RNA4 untranslated leader sequence," Plant Science 94(1/2):139 1993				

Examiner Signature	MARK NAVARRO	Date Considered	2/17/04
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~	C9	ELLIS, R.W., "New Technologies for Making Vaccines," in Vaccines, Plotkin, S.A. and Mortimer, Jr. E.A., eds., W.B. Saunders Co., Philadelphia (1988), Ch. 29, pp. 568-575		
~	C10	ESTRUCH, J.J. et al., "Transgenic plants: an emerging approach to pest control." Nat Biotechnol. 1997 Feb;15(2):137-41.		
~	C11	FISHER, DE and Guiltinan, MJ, "Rapid, Efficient Production of Homozygous Transgenic Tobacco Plants with <i>Agrobacterium tumefaciens</i> : A Seed-to-Seed Protocol," Plant Mol. Biol. Reporter 13(3):278-289 (1995)		
~	C12	FRALEY RT, et al., "Expression of bacterial genes in plant cells." Proc Natl Acad Sci U S A. 1983 Aug;80(15):4803-7.		
~	C13	FROMM, H. et al., "An octopine synthase enhancer element directs tissue-specific expression and binds ASF-1, a factor from tobacco nuclear extracts." Plant Cell. 1989 Oct;1(10):977-84.		
~	C14	GALLIE DR, et al., "The 5'-leader sequence of tobacco mosaic virus RNA enhances the expression of foreign gene transcripts in vitro and in vivo." Nucleic Acids Res. 1987 Apr 24;15(8):3257-73.		
~	C15	GOMORD V, et al., "The C-terminal HDEL sequence is sufficient for retention of secretory proteins in the endoplasmic reticulum (ER) but promotes vacuolar targeting of proteins that escape the ER." Plant J. 1997 Feb;11(2):313-25.		
~	C16	HALL et al. "Major surface antigen gene of a human malaria parasite cloned and expressed in bacteria," Nature 311:379 (1984).		
~	C17	HASEGAWA A, et al., "The complete sequence of soybean chlorotic mottle virus DNA and the identification of a novel promoter." Nucleic Acids Res. 1989 Dec 11;17(23):9993-10013.		
~	C18	HASELOFF J, et al., "Removal of a cryptic intron and subcellular localization of green fluorescent protein are required to mark transgenic Arabidopsis plants brightly." Proc Natl Acad Sci U S A. 1997 Mar 18;94(6):2122-7.		
~	C19	HAQ TA, et al., "Oral immunization with a recombinant bacterial antigen produced in transgenic plants." Science. 1995 May 5;268(5211):714-6.		
~	C20	HELLIWELL CA, and Gray JC. "The sequence surrounding the translation initiation codon of the pea plastocyanin gene increases translational efficiency of a reporter gene." Plant Mol Biol. 1995 Nov;29(3):621-6.		
~	C21	HERRERA et al. "Conserved Polypeptides of Plasmodium falciparum as Malaria Vaccine Candidates?", Acta Leidensia, 60(1):107-110 (1991).		
~	C22	HERRERA et al. "Immunization of Aotus monkeys with Plasmodium falciparum blood-stage recombinant proteins," Proc. Natl. Acad. Sci. USA 87:4017 (1990).		
~	C23	HOLDER et al. "Immunization against blood-stage rodent malaria using purified parasite antigens," Nature 294:361 (1981).		
~	C24	HOLDER et al., "A hybrid gene to express protein epitopes from both sporozoite and merozoite surface antigens of Plasmodium falciparum," Parasitology, 97:373-382 (1988).		
~	C25	HOLDER, A.A. et al., "Immunization against Plasmodium falciparum with recombinant polypeptides produced in Escherichia coli," Parasite Immunology, 10(6):607-617 (1988).		
~	C26	HOLDER et al., "Primary Structure of the Precursor to the three major surface antigens of Plasmodium falciparum merozoite," Nature, 317:270-273 (1985).		
~	C27	HOLDER et al., "Processing of the precursor to the major merozoite surface antigens of Plasmodium falciparum," Parasitology, 94:199-208 (1987).		
~	C28	HUI et al. "Serum from Pf195 protected Aotus Monkeys Inhibit Plasmodium falciparum growth in Vitro," Exp. Parasitol. 64:519 (1987).		
~	C29	IANNACONE, R. et al., "Specific sequence modifications of a cry3B endotoxin gene result in high levels of expression and insect resistance." Plant Mol Biol. 1997 Jun;34(3):485-96.		

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Sheet 3 of 4

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First Named Inventor CHANG, Sandra P.
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~	C30	JOBLING SA, and GEHRKE L. "Enhanced translation of chimeric messenger RNAs containing a plant viral untranslated leader sequence." Nature. 1987 Feb 12-18;325(6105):622-5.	
~	C31	JOSHI RL, et al., "BSMV genome mediated expression of a foreign gene in dicot and monocot plant cells." EMBO J. 1990 Sep;9(9):2663-9.	
~	C32	KNAPP, B. et al. "A histidin alanine rich recombinant antigen protects aotus monkeys from P. Falciparum infection." Behring Inst. Mitt. 82:349-59 (1988).	
~	C33	KOZIEL MG, et al., "A cauliflower mosaic virus promoter directs expression of kanamycin resistance in morphogenic transformed plant cells." J Mol Appl Genet. 1984;2(6):549-62.	
~	C34	KUMAR S, et al., "Immunogenicity and efficacy in aotus monkeys of four recombinant Plasmodium falciparum vaccines in multiple adjuvant formulations based on the 19-kilodalton C terminus of merozoite surface protein 1." Infect Immun. 2000 Apr;68(4):2215-23.	
~	C35	LEW et al. "A protective monoclonal antibody recognizes a linear epitope in the precursor to the major merozoite antigens of Plasmodium chabaudi adami." Proc. Natl. Acad. Sci. USA 86:3768 (1989).	
~	C36	LOCHER CP, et al., "Plasmodium falciparum: gp195 tripeptide repeat-specific monoclonal antibody inhibits parasite growth in vitro." Exp Parasitol. 1996 Oct;84(1):74-83.	
~	C37	LUMBRERAS, V. et al., "The use of an alternative promoter in the Arabidopsis thaliana HMG1 gene generates an mRNA that encodes a novel 3-hydroxy-3-methylglutaryl coenzyme A reductase isoform with an extended N-terminal region." Plant J. 1995 Oct;8(4):541-9.	
~	C38	MA JK, et al., "Generation and assembly of secretory antibodies in plants." Science. 1995 May 5;268(5211):716-9.	
~	C39	MAITI IB, and Shepherd RJ. "Isolation and expression analysis of peanut chlorotic streak caulimovirus (PCISV) full-length transcript (FLT) promoter in transgenic plants." Biochem Biophys Res Commun. 1998 Mar 17;244(2):440-4. Errata appears in Biochem Biophys Res Commun. 1998 Jul 9;248(1):210.	
~	C40	MASON HS, et al., "Expression of hepatitis B surface antigen in transgenic plants." Proc Natl Acad Sci U S A. 1992 Dec 15;89(24):11745-9.	
~	C41	MITRA A, et al., "A Chlorella virus gene promoter functions as a strong promoter both in plants and bacteria." Biochem Biophys Res Commun. 1994 Oct 14;204(1):187-94.	
~	C42	MAJARIAN et al. "Passive Immunization against Murine Malaria with an IgG3 Monoclonal Antibody." J. Immunol. 132:3131 (1984).	
~	C43	MOFFAT AS. "Exploring transgenic plants as a new vaccine source." Science. 1995 May 5;268(5211):658-660.	
~	C44	MURPHY, V.F. et al., "Expression of hybrid malaria antigens in insect cells and their engineering for correct folding and secretion." Parasitology. 100 pt. 2:177-183 (1990).	
~	C45	ODINK K.G. et al., "Expression of cloned cDNA for a major surface antigen of Plasmodium falciparum merozoite." FEBS Lett. (1984) 108-12.	
~	C46	OHME-TAKAGI, M. et al., "The effect of sequences with high AU content on mRNA stability in tobacco." Proc Natl Acad Sci U S A. 1993 Dec 15;90(24):11811-5.	
~	C47	PATARROYO et al. "A synthetic vaccine protects humans against challenge with asexual blood stages of Plasmodium falciparum malaria." Nature 332:158 (1988).	
~	C48	PATARROYO et al. "Induction of protective immunity against experimental infection with malaria using synthetic peptides." Nature 328:629 (1987).	

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~	C49	PATARROYO et al. "Protective Synthetic Peptides against Experimental Plasmodium falciparum-Induced Malaria," Vaccines 87 (Brown, Chanock, Lerner, ed.) Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY. 117-124 (1987).
~	C50	PERRIN et al. "Antimalarial Immunity in Saimiri Monkeys," J. Exp. Med. 160:441 (1984).
~	C51	POTTER, RH and JONES, MGK, Plant Gene Transfer, in Plant and Molecular Biology, A Laboratory Manual, Clark, M. S. (ed.) Springer, chap. 8, pp. 400-426 (1997)
~	C52	RODRIGUEZ et al. "Studies in Owl Monkeys Leading to the Development of a Synthetic Vaccine Against the Asexual Blood Stages of Plasmodium Falciparum," Am. J. Trop. Med. Hyg. 43:339 (1990).
~	C53	RUEBUSH et al. "Immunization of Owl Monkeys with a Combination of Plasmodium Falciparum Asexual Blood-Stage Synthetic Peptide Antigens," Am. J. Trop. Med. Hyg. 43:355-366 (1990).
~	C54	SANGER M, et al., "Characteristics of a strong promoter from figwort mosaic virus: comparison with the analogous 35S Mar.14(3):433-43.
~	C55	SAUL et al., Second African Malaria Vaccine Testing Network Meeting, Accra, Ghana, Nov. 24-26, 1997
~	C56	SCHWARZ et al., "Structural Diversity of the Major Surface Antigen of Plasmodium falciparum Merozoites," Mol. Cell. Biol., 6(3):964-968 (1986).
~	C57	SHIRSAT, A. et al., "Sequences responsible for the tissue specific promoter activity of a pea legumin gene in tobacco," Mol Gen Genet. 1989 Jan;215(2):326-31.
~	C58	SIDDQUI et al. "Merozoite surface coat precursor protein completely protects Aotus monkeys against Plasmodium falciparum malaria," 1987. Proc. Natl. Acad. Sci. USA 84:3014.
~	C59	SIMONS PC, et al., "Production of correctly processed human serum albumin in transgenic plants," Biotechnology (N Y). 1990 Mar;8(3):217-21.
~	C60	SMILEK, D. et al., "A single amino acid change in myelin basic protein peptide confers the capacity to prevent rather than induce EAE," Proc. Natl. Acad. Sci. USA 88:9633-37 (1991).
~	C61	SOLTYSIK, "Structure/function studies of QS-21 adjuvant: assessment of triterpene aldehyde and glucuronic acid roles in adjuvant function," Vaccine 1995, 13(15):1403-1410
~	C62	STAUB, JM et al., "High-yield production of a human therapeutic protein in tobacco chloroplasts," Nat. Biotech. 18:333-338 (2000)
~	C63	STOWERS AW, et al., "A recombinant vaccine expressed in the milk of transgenic mice protects Aotus monkeys from a lethal challenge with Plasmodium falciparum." Proc Natl Acad Sci U S A. 2002 Jan 8;99(1):339-44. Epub 2001 Dec 18.
~	C64	STOWERS AW, et al., "Efficacy of two alternate vaccines based on Plasmodium falciparum merozoite surface protein 1 in an Aotus challenge trial." Infect Immun. 2001 Mar;69(3):1536-46.
~	C65	TANABE, K. et al., "Allelic Dimorphism in a Surface Antigen Gene of the Malaria Parasite Plasmodium falciparum," J. Mol. Biol., 195:273-287 (1987).
~	C66	TIAN, Y.C. et al., "Insect resistance of transgenic tobacco plants expressing delta-endotoxin gene of Bacillus thuringiensis." Chin J Biotechnol. 1991;7(1):1-13.
~	C67	TURPEN TH, et al., "Malarial epitopes expressed on the surface of recombinant tobacco mosaic virus." Biotechnology (N Y). 1995 Jan;13(1):53-7.

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